K103021

NOV - 4 2011

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 09/08/2011

1. Submission Sponsor

	Submitter
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2. Submission Correspondent

LK Consulting Group
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3. Device

- Trade Name: Element™ *plus* Blood Glucose Monitoring System (IGM-0021B)
- Classification Name: Glucose test system, Quality control material (assayed and unassayed)
- Classification regulation: 21 CFR Part 862.1345, 21 CFR Part 862.1660
- Product Code: NBW, CGA, JJX

4. Predicate Device:

Evolution™ Blood Glucose Test System (K072369), Infopia Co., Ltd.

5. Description:

Element™ *plus* Blood Glucose Monitoring System is comprised of test meter, test strip and control solutions. Element™ *plus* blood glucose test meter is substantially identical with the predicate device (Evolution™: K072369). The minor difference is that Element™ *plus* test meter has voice function, which Evolution™ test meter does not have. The voice function can be used as an aid for the users to hear the test results, setting conditions and warning messages. This added function is intended to aid users' convenience.
Element™ *plus* blood glucose test strip is identical with the predicate device (Evolution™: K072369) except the cover design of the test strip. Element™ *plus* glucose control solutions are

also exactly same as Evolution™ control solutions.

6. Indications for use:

The Element™ *plus* Blood Glucose Monitoring System is for the quantitative measurement of glucose in capillary whole blood taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh. Element™ *plus* Blood Glucose Testing System is for in vitro diagnostic use and is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Element™ *plus* Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element™ *plus* Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in the management of diabetes. Alternative site Testing (ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh) should be done during steady- state times when glucose is not changing rapidly.

The Element Plus Test strip are for use with the Element Plus Blood Glucose Meter to quantitatively measure glucose (sugar) in capillary whole blood samples drawn from ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

This meter contains some speaking functions but has not been validated for use by the visually impaired.

7. Comparison to the Cleared Device

The modified device has the same technological characteristics as the current legally marketed predicate device, Evolution™ (K072369).

8. Performance Data

Clinical: The clinical performance evaluation using the Element™ *plus* Blood Glucose Monitoring System components were conducted for purpose of validating the consumer use for the user and the professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Element™ *plus* Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfection Studies: CaviWipes™ Disinfecting Towelettes (EPA Reg. No: 46781-8) was validated demonstrating complete inactivation of live virus for use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and lancing device after 1,095 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusion

The conclusion drawn from the clinical and nonclinical tests is that the Element™ *plus* Blood Glucose Monitoring System is as safe, as effective and performs as well as the legally marketed predicate device, the Evolution™ (K072369).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 04 2011

Infopia Co., Ltd
c/o Priscilla Chung
LK Consulting Group
951 Starbuck St. Unit J
Fullerton, CA 92833 US

Re: k103021
Trade Name: Element plus Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System.
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: October 4, 2011
Received: October 7, 2011

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K103021

Device Name: Element ™ *plus* Blood Glucose Monitoring System

(For single patient-home use)

Indication For Use:

The Element ™ *plus* Blood Glucose Monitoring System is for the quantitative measurement of glucose in capillary whole blood taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh. Element ™ *plus* Blood Glucose Testing System is for in vitro diagnostic use and is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Element ™ *plus* Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element ™ *plus* Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in the management of diabetes. Alternative site Testing (ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh) should be done during steady- state times when glucose is not changing rapidly.

The Element ™ *plus* Test Strips are for use with the Element™ plus Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

This meter contains some speaking functions but has not been validated for use by the visually impaired.

Prescription Use ____	And/Or	Over the Counter Use __X__
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103021